

CHAPTER 61-04-10

CLIA WAIVED LABORATORY TESTS

Section	
61-04-10-01	Definitions
61-04-10-02	Education Requirements for Pharmacists to Perform CLIA Waived Laboratory Tests
61-04-10-03	Minimum Quality Standards Required
61-04-10-04	Proper CLIA Registration
61-04-10-05	Notification of the Board of Pharmacy

61-04-10-01. Definitions. For purposes of this chapter:

1. "CLIA" means the federal Clinical Laboratory Improvement Act of 1988, as amended.
2. "OSHA" means the federal occupational safety and health administration.
3. "Portfolio review" means a review by the board of a pharmacist's records of proficiency testing logs, control testing logs, and records of patient tests performed to determine that a pharmacist is continuously and consistently providing a service in a quality and competent manner.

History: Effective December 1, 1999.

General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3

61-04-10-02. Education requirements for pharmacists to perform CLIA waived laboratory tests. A pharmacist must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by that section:

1. Successfully complete a board-approved course of study that incorporates principles of general laboratory procedures to include, at a minimum:
 - a. Infection control;
 - b. OSHA requirements;
 - c. Proper technique to collect laboratory specimens;
 - d. Recognized screening and monitoring values; and
 - e. Quality control.
2. Recertify every three years by portfolio review or reeducation.

3. Successfully complete training for each specific instrument used to perform CLIA waived laboratory tests.

History: Effective December 1, 1999.

General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3

61-04-10-03. Minimum quality standards required. Pharmacists performing CLIA waived laboratory tests must meet the following standards:

1. Develop and maintain a procedural manual that includes the following areas:
 - a. Quality control;
 - b. Infection control;
 - c. Hazardous waste disposal;
 - d. Recordkeeping; and
 - e. Test result reporting.
2. Maintain participation in a nationally recognized proficiency program approved by the board.

History: Effective December 1, 1999.

General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3

61-04-10-04. Proper CLIA registration. The pharmacist-in-charge of a licensed pharmacy performing tests or any pharmacist operating in a facility not licensed by the board is responsible for ensuring that the facility where the tests are performed has a proper CLIA certificate.

History: Effective December 1, 1999.

General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3

61-04-10-05. Notification of the board of pharmacy. The pharmacist-in-charge of a licensed pharmacy that has obtained a CLIA certificate or any pharmacist operating in a facility not licensed by the board of pharmacy must notify the board prior to the initial performance of any CLIA waived tests. The notification must specify the types of tests which are to be performed.

History: Effective December 1, 1999.

General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3